

DEPARTMENT OF HEALTH SERVICES
COUNTY OF LOS ANGELES

SUBJECT: **CONTROLLED DRUGS CARRIED ON ALS UNITS**

(PARAMEDIC)
REFERENCE NO. 702

PURPOSE: To ensure accountability for all controlled drugs issued to ALS units.

AUTHORITY: Health and Safety Code, Chapter 5, 1797.220 and 1798
California Business and Professions Code, Section 4005 and 4119(4)(5)
Department of Justice, DEA Regulations, Title 21, Code of Federal Regulations,
Section 1300-1360
Controlled Substances Act, 21 UNC 801-890

PRINCIPLES:

1. Effective controls and procedures are essential to guard against theft and diversion of controlled substances due to the risks associated with mishandling these drugs.
2. Controlled drugs will be restocked only with a full account of drugs administered, wasted, or lost.
3. Controlled drugs issued from County-operated pharmacies are intended for use within Los Angeles County except as otherwise specified in this policy. County-issued controlled drugs remain the property of Los Angeles County after being issued to paramedic provider agencies and when carried on ALS units.
4. Providers may only carry one narcotic analgesic on the ALS units. Provider Agency Medical Directors may request to carry Fentanyl by contacting the EMS Agency's Medical Director.

QUANTITIES OF CONTROLLED DRUGS TO BE CARRIED ON ALS UNITS:

Fentanyl: 100mcg unit dose, minimum amount 500mcg not to exceed 1500mcg unless otherwise approved by the EMS Agency Medical Director, the Provider Agency Medical Director or as dictated by supply.

Morphine sulfate: 4mg unit dose, minimum amount 32mg not to exceed 60mg unless otherwise approved by the EMS Agency Medical Director, the Provider Agency Medical Director or as dictated by supply.

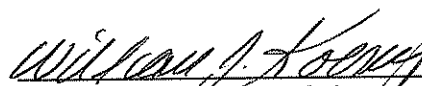
Midazolam (Versed®): 5mg unit dose, minimum amount 20mg not to exceed 40mg unless otherwise approved by the EMS Agency Medical Director, the Provider Agency Medical Director, the Provider Agency Drug Authorizing Physician or as dictated by supply.

EFFECTIVE: 1-7-98
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SUPERSEDES: 01-01-13

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APPROVED:


Director, EMS Agency


Medical Director, EMS Agency

POLICY:

I. Provider Agencies May Obtain Controlled Drugs Through:

- A. A County operated hospital pharmacy (with approval from the EMS Agency) utilizing the procedure outlined in this policy.
- B. A Provider Agency Medical Director who meets the qualifications of Reference No. 411, Provider Agency Medical Director if they agree to authorize such procurement or a Provider Agency Drug Authorizing Physician as outlined in Reference. No. 410, Drug Authorizing Physician for Provider Agencies.

II. Controlled Drug Resupply Through a County Operated Hospital Pharmacy:

A. EMS Agency responsibilities:

- 1. Assign each provider agency that chooses to resupply controlled drugs through a County operated hospital to one or more County facilities.
- 2. Supply each provider agency with a locked bag in which to store controlled drugs while in transit between the pharmacy and the provider agency.
- 3. Resupply controlled drugs on a one-for-one basis utilizing the procedure outlined in this policy.
- 4. Report the theft or loss of any controlled substances to the issuing pharmacy, whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them.

B. Provider Agency Responsibilities:

- 1. Provider agency controlled drug policies and procedures shall be consistent with Ref. No. 702 and be submitted to the EMS Agency for initial review and approval.
 - a. Any subsequent changes to policies and procedures must be submitted to the EMS Agency for review and approval.
- 2. Provide the County pharmacists with the names and original signatures of individuals authorized to pick up and transport controlled drugs. A copy of this document shall be provided to the EMS Agency.
 - a. Submit a single list of names (not copies of drivers' licenses or other ID cards) on departmental or company letterhead.
 - b. Update the list annually, no later than June 30th
- 3. Identify, in the provider agency's internal policy, one or more individuals responsible for the key to the controlled drug transit bag. The County pharmacist will maintain a second key at the pharmacy.

4. Ensure that the on-duty paramedic is responsible for the security of the drugs at all times. If the department uses a non-key system, such as a keypad or padlock type, the internal controlled substance policy should indicate how the combination is kept secure. Ensure adequate security to guard against theft and diversion during controlled drug transport and distribution.
5. Utilize County-issued controlled drugs outside of Los Angeles County only in the event of wildfires, disasters, terrorist responses or other unanticipated events.
6. Restock controlled drugs only from the assigned Department of Health Services (DHS) pharmacy to prevent intermingling of controlled drug stock.
7. Provider agencies using an EMS Agency approved electronic patient care record (ePCR) will develop a process/procedure, approved by the EMS Agency and the assigned County Pharmacy, on the type of paper documentation required for medication replacement.

C. Replacement Procedure for Controlled Drugs Administered in the Field:

1. Providers shall:
 - a. Present the blue copy of the EMS Report Form, or ePCR or a uniquely identifiable document for each patient to whom a controlled drug was administered.
 - b. Present a photo identification (employee ID, driver's license, etc.) to verify identity at the pharmacy.
2. Pharmacists shall:
 - a. Stamp and initial the blue copy of the EMS Report Form (ePCR document) utilizing the EMS Agency-issued stamp.
 - b. Replace the controlled drugs utilizing the locked transport bag.
 - c. Return the blue copy (or the ePCR documentation) to provider agency personnel.

D. Replacement Procedure for Expired-or Broken Controlled Drugs:

1. Provider agencies shall:
 - a. Complete Reference No. 702.1, Expired/Broken Controlled Drug Pharmacy Reporting Form, and maintain a copy in the provider agency's controlled drug file.

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- b. Present the completed Reference No. 702.1 to the issuing pharmacy along with the expired drug(s) for disposal in accordance with all applicable state and federal regulations.
 - c. If requesting replacement of controlled drugs due to breakage, complete Ref. No. 702.1 and provide the broken container to the issuing pharmacy.
 - 2. Pharmacists shall:
 - Replace the controlled drug following their facility's approved procedure.
 - E. Replacement Procedure when the Blue Copy of the EMS Report Form (or the ePCR) is Missing:
 - 1. Paramedics shall notify the on-duty captain, battalion chief or supervisor that the blue copy is missing. A written report summarizing the incident shall be submitted to the EMS Agency that:
 - a. Describes what happened to the Blue Copy of the form (or the ePCR).
 - b. Is signed and dated by the reporting party, the on-duty captain or supervisor, the battalion chief or general manager.
 - 2. The incident report and a copy of the EMS Report Form shall be forwarded to the paramedic coordinator or the individual responsible for controlled drug procurement.
 - 3. The paramedic coordinator or responsible individual shall review the documents and hand deliver copies to the EMS Agency.
 - 4. EMS Agency staff shall review and validate the documents and generate a letter to the provider agency's assigned County pharmacy authorizing replacement of the controlled drugs. The original copy of the authorization, which expires in 14 days, is handed to the paramedic coordinator or responsible individual to carry to the pharmacy.
- III. Controlled Drug Replacement Through a Non-County Supplier:
- A. Provider agencies that have requested EMS Agency oversight of their controlled drug program shall develop policies and procedures, approved by their Provider Agency Medical Director and/or Drug Authorizing Physician, to ensure that all controlled drugs are obtained, maintained, and distributed in a secure manner consistent with local, state, and federal regulations.
 - B. Such policies and procedures shall be submitted to the EMS Agency for review and approval unless the Provider Agency Medical Director/Drug Authorizing Physician wants to assume sole responsibility for procurement, storage and security of controlled substances. In that case, the Provider Agency Medical Director and Provider Agency Fire Chief (or CEO/President) shall submit Ref. No. 702.4, Provider Agency Medical Director Notification of Controlled Substance Program Implementation.

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- C. Provider agencies that operate a controlled drug program without EMS Agency oversight shall submit Ref. No. 702.4 under the following circumstances:

1. Upon initial request to develop a controlled drug program without EMS Agency oversight.
2. At the time of the EMS Agency annual program review.
3. Any change in the provider agency medical director.

IV. Controlled Drug Security

- A. Controlled drug security requirements apply to all provider agencies, whether drugs are ordered through the Provider Agency Medical Director, Drug Authorizing Physician or the EMS Agency Medical Director.
- B. Paramedics assigned to an advanced life support (ALS) unit shall be responsible for maintaining the correct controlled drug inventory and security of the narcotic keys (or confidentiality of the keypad/padlock combination) for their assigned unit at all times.
- C. Controlled drugs shall not be stored in any location other than on ALS units unless authorized by the EMS Agency. The initial authorization process requires EMS Agency inspection of the storage facility and approval of the provider agency internal policy specifying the location, security, access and procedure for obtaining drugs from the controlled drug cache. (This requirement does not apply to provider agencies that meet the terms of Ref. No. 702.4).
- D. Fentanyl or morphine and midazolam shall be secured on the ALS units under double lock. Provider agencies that have more than one approved ALS unit must have unique double locking mechanisms for each ALS unit.
- E. Daily Inventory Procedures
 1. Controlled drugs shall be inventoried by two paramedics at least daily and anytime there is a change in personnel.
 2. The key to access controlled drugs shall be in the custody of the individual who performed the inventory.
 3. The Daily Controlled Drug and Key Inventory Form, Reference No. 702.2 or its equivalent, shall be co-signed with the names of the relinquishing and the receiving paramedic. Entries shall be in blue or black ink only.

NOTE: Errors shall be corrected by drawing a single line through the incorrect wording; the writing underneath the single line must remain readable. The individual making the change should initial adjacent to their correction. Correction fluid or other erasure material is not permitted.

4. The Daily Controlled Drug and Key Inventory Form, Reference No. 702.2 or its equivalent, must be maintained by the provider agency for a minimum of three years. An entry shall be made on this form for each of the following situations:

- a. Change of shift.
- b. Any change to the narcotic inventory.
- c. Any time there is a change of responsible personnel

NOTE: Providers authorized to participate in the 1:1 Staffing Program for Interfacility Transports are required to inventory controlled drugs at the end of the specified shift, when two paramedics are available to count and co-sign for the drugs.

5. Provider agencies that restock controlled drugs from County operated pharmacies shall forward copies of Reference No. 702.2, Monthly Controlled Drug Storage Inspection Form or its equivalent, to their assigned DHS pharmacy no later than the 30th day of the following month.

F. Lost or Missing Controlled Substances

1. Issued by a County Operated Pharmacy
 - a. Any lost or missing controlled substances or discrepancy in the controlled drug count is to be reported by the following business day to the Department of Health (DHS) pharmacy that supplied the drugs and the EMS Agency. The follow up paperwork shall be submitted within five business days.
 - b. A police report is required for any suspected lost or missing controlled substances.
 - c. Any loss or discrepancy shall also be reported to the paramedic coordinator, and the Provider Agency Medical Director or other authorized physician.
 - d. Any lost or missing controlled substances shall be documented on Reference No. 702.5 Missing Lost Controlled Drug Pharmacy Reporting Form, and shall initiate supervisory review at the involved provider agency. The original of the completed form will be presented to the DHS pharmacy that dispensed the drugs.
 - e. Replacement of lost or missing controlled substances requires that all investigative documentation be submitted to the EMS Agency (police report, personnel statements, supervisor's follow-up, processes implemented to decrease the likelihood of future occurrences, etc.). Upon review and approval of the documentation, the EMS Agency will provide written authorization for replacement of the controlled substance(s).

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- f. If a provider agency's internal investigation into a controlled drug loss exceeds thirty days, the provider shall submit a status update to the issuing DHS pharmacy and the EMS Agency at the 30th day.
 - 2. Authorized by a Provider Agency Medical Director or Drug Authorizing Physician.
 - a. Provider agencies approved to operate under Ref. No. 702.4 shall have policies/procedures in place consistent with local, state, and federal regulations on mandated reporting.
 - b. Any lost, missing or discrepancy shall be reported by the following business day to the paramedic coordinator, the EMS Agency, and the authorizing Provider Agency Medical Director or Drug Authorizing Physician.
 - c. Any significant loss, breakage or discrepancy in the count requires notification to the Drug Enforcement Administration, utilizing DEA Form 106 or electronically via the DEA web site, within one business day of discovery.
 - d. Any loss shall initiate supervisory review at the involved provider agency. If a provider agency's internal investigation into a controlled drug loss exceeds 30 days, the provider shall submit a status update to the Provider Agency Medical Director and the EMS Agency.
 - G. Disposal of controlled substances issued by a non-county pharmacy
 - 1. The provider agency shall dispose of expired controlled substances through one, or a combination of the following:
 - a. Utilizing a DEA licensed pharmaceutical reverse distributor.
 - b. Following the guidelines outlined in the Code of Federal Regulations, Section 1307.21, Procedure for Disposing of Controlled Substances.
- V. Record Keeping
- A. All controlled drugs issued to a provider agency must be accounted for. The provider agency shall retain a copy of the EMS Report Form (or an ePCR) for each patient to whom a controlled drug was administered and maintain it with any completed Missing/Expired Controlled Drug Reporting Forms, drug orders, invoices or other associated documentation in a separate file for a minimum of three years.
 - B. Each controlled drug use must be documented on the EMS Report Form (or ePCR). If the total amount of the drug is not administered, the remaining amount shall be wasted at the receiving facility as follows:
 - 1. Document wasted narcotics (partial or whole) in the "Narcotic Waste/Witness" section of the EMS Report Form or ePCR, including the amount wasted.
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2. Obtain the printed name and signature of the witness who observed the disposal of the remaining solution. (registered nurse, physician, pharmacist).
- C. In addition to the local EMS Agency and the provider agency, controlled drug inventories and logs are subject to inspection by the issuing pharmacy, the California Board of Pharmacy, and agents of the Bureau of Narcotic Enforcement

Administration of the Department of Justice, Federal Drug Enforcement Administration.

CROSS REFERENCES:**Prehospital Care Manual:**

- Reference No. 410, **Provider Agency Drug Authorizing Physician**
Reference No. 411, **Provider Agency Medical Director**
Reference No. 606, **Documentation of Prehospital Care**
Reference No. 607, **Electronic Submission of Prehospital Data**
Reference No. 701, **Supply and Resupply of Designated EMS Provider Units/Vehicles**
Reference No. 702.1, **Expired/Broken Controlled Drug Pharmacy Reporting Form**
Reference No. 702.2, **Daily Controlled Drug and Key Inventory Form (Page 1 of 2)**
Monthly Drug Storage Inspection Form (Page 2 of 2)
Reference No. 702.3, **County Operated Pharmacy Contact Numbers for Reporting Loss of Controlled Drugs**
Reference No. 702.4, **Provider Agency Medical Director Notification of Controlled Substance Program Implementation**
Reference NO. 702.5 **Lost/Missing Controlled Drug Pharmacy Reporting Form**